

## REMARKS

Claims 1-12 are pending and rejected.

Claim 11 has been amended to correct informalities by adding the verb "includes".

Support for this amendment is in the specification on page 4, line21.

No new matter has been added by these amendments.

### Claim Objections

Claim 11 is objected to for informalites. In response, claim 11 has been amended to correct the informalities and overcomes the objections.

### Claim Rejections under 35 USC § 102

Claims 1-12 are rejected under 35 USC § 102(b) as allegedly being anticipated by Bedbrook et al. (WO 97/01952). In particular, the Office Action contents that the vector described in Bedbrook comprises three copies of the construct arranged as inverted repeats and a LacA polylinker as a spacer (page 6, lines 2-4).

Applicants respectfully disagree with this rejection.

The legal test for anticipation under 35 U.S.C. § 102 requires that each and every element of the claimed invention be disclosed in a prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the public in possession of the invention. W.L. Gore Assoc. v. Garlock, Inc., 721 F.2d 1540, 1554 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1994); In re Donohue, 766 F.2d 531 (Fed. Cir. 1985). Anticipation under 35 U.S.C. § 102 requires identity of invention. Scripps Clinical & Research Fdn. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991).

Bedbrook describes the use of the phenomenon called "sense" gene silencing or "sense co-suppression" as opposed to "antisense suppression" by introducing into the genome of an organism an additional copy of an endogenous gene sequence. The inserted sequence may be a full-length copy or, preferably, truncated. This reference does not describe the present invention, however, the use of arrows in Figure 4 has caused confusion.

The arrows in Figure 4 are showing the direction of transcription. Figure 4 shows promoters (p35S), coding regions (ACCS) and transcription termination regions (nos3'). Also shown are three copies of a marker gene (promoter (pnos)-coding (NPTII) terminator (ocs3')).

Gene transcription always begins at the promoter end and then runs to the 3' region. Since the direction of transcription does not suddenly change part way along a sequence, what the diagram actually shows is that all the units with oppositely opposed arrows are actually on different strands of DNA. So all the sequences drawn on left pointing arrows are on a different strand from those arrows pointing right. The actual sequences are the same - p35S-ACCS-nos3'-is the gene but two copies of it are on one strand of DNA and the third copy is on the other strand of DNA. There are no transcribable inverted repeats in this diagram in spite of the use of the term in the description given on page 15. The complementary sequence of a region that exists on the other strand will obviously occur but using the example below to represent the ACCS sequence the outcome is as follows:

START-----→STOP
Strand 1      5'-Promoter-ATBCTAG....-terminator...a/s terminator- CTAGCAT-a/s promoter-3'
Strand 2      3'-a/s promoter -TACGATC....a/s terminator....    terminator-GATCGTA- promoter -5'
STOP ←-----←START

Just for the avoidance of doubt, the complementary sequence of a promoter (shown as a/s promoter) is non-functional. The DNAs transcribable on Strands 1 and 2 here are identical.

In comparison, a construct of the present invention looks like this:

START-----→STOP
Strand 1      5'-prmoter-ATGCTAGCTAGCAT....-terminator....3'
Strand 2 3'-a/s promoter-TACGATCGATCGTA ..a/s terminator-5'
-----NO TRANSCRIPTION-----

In other words, what claim 1 is seeking to protect is:

----ATGCTAG(X)<sub>n</sub>CTAGCAT----

where X is an oligonucleotide which may or may not (n=0,1,2 etc) be present.

The foregoing is somewhat simplified, for the purpose of illustration and should not be taken to infer that the sequence/repeat sequence must of necessity be of any particular part of the gene. It is clear from our description that parts of promoters or 5' untranslated regions, or even 3' regions may be used. See page 5 in specification for example.

The above remarks overcome this rejection, and Applicants request its withdrawal.

### **Claim Rejection under 35 USC § 103**

Claims 1-12 are rejected under 35 USC § 103(a) as allegedly obvious over Dorer et al. (Cell, 77:993-1002, 1994). In particular, the Office Action contends that Figures 1 and 3 of Dorer suggest a vector with inverted repeats.

Applicants respectfully disagree with this rejection.

A finding of obviousness under § 103 requires a determination of the scope and content of the prior art, the level of ordinary skill in the art, the differences between the claimed subject matter and the prior art, and whether the differences are such that the subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. Graham v. Deere, 383 U.S. 1 (1966). The relevant inquiry is whether the prior art suggest the invention, and whether the prior art provides one of ordinary skill in the art with a reasonable expectation of success. In re O'Farrell 853 F.2d 894, 903 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art and not in the Applicants' disclosure. In re Vaeck 947 F.2d 488 (Fed. Cir. 1991).

The cited reference does not make obvious the presently claimed invention.

Dorer uses the term "inverted", for example, in the legend to Figure 2, page 994, where they discuss "class I inverted duplication line." Figure 3, on page 995, shows the structure of the various lines and class I is at the top, showing arrows pointing in opposite directions. However, the first full paragraph below Figure 3 describes what they mean and it says "The most common arrangement of repeats (Class I)... was a duplication in which the second transposon ... was inserted in a reversed direction." So, using the example above, the sequence would be a 5'-ATGCTAGGATCGTA-3'. Arrows can be used in diagrams such as these either to indicate the direction of transcription or the orientation of the reading frame. In Dorer's Figure 2, they are indication orientation of the reading frame: if they were meant to indicate direction of

transcription the arrow would run over the full length of the sequence because in any one sequence transcription will always run from the 3' promoter in a 5' direction over the full length of contiguous nucleotides until a stop codon is encountered. So the left and right portions of Dorer's sequence are on different strands and would be physically incapable of folding or bending to form a hairpin or stem-loop structure: the two pieces of RNA would be separate after transcription.

Since Dorer does not suggest, much less teach, the present invention, it does not make obvious the invention. Applicants request its withdrawal.

If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 50-1744 of Syngenta Biotechnology Inc.

Respectfully submitted,



Mary Kakefuda  
Attorney for Applicant  
Registration No. 39,245  
Telephone: 919-765-5071

Syngenta Biotechnology, Inc.  
P. O. Box 12257  
Research Triangle Park, NC 27709-2257

Date: December 16, 2004